59th Medical Wing
Office of the Chief Scientist

59 MDW Research Reference Guide

P.I. Handbook

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If you have any questions or comments, please email usaf.jbsa.59-mdw.mbx.59-mdw-ST@mail.mil

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FOREWARD

The 59th Medical Wing Chief Scientist provides the strategic vision, direction, oversight, project management support and technical resources to advance medical modernization efforts with a unique focus on research activities. The research portfolio is requirements-driven to address unique military scientific needs in trauma critical care, clinical and rehabilitative medicine, diagnostics, therapeutics and medical modeling and simulation training. The goal is to advance DoD Joint capabilities and improve military health and readiness from the battlefield to the market-place interfacing with partners in the Services, academia, private sector, and other government agencies by transitioning scientific findings to the operational environment and patient bedside, to best practice.

This guide is a quick reference to the numerous specialized Principal Investigators involved in military medical research in and around the San Antonio, Texas, area. Additional information regarding the 59th Medical Wing, our office and research portfolio is at: http://www.59mdw.af.mil/Home.aspx; http://www.59mdw.af.mil/Units/ChiefScientist-ST.aspx; and https://kx.afms.mil/kj/kx8/59MDWScienceAndTechnology/Pages/home.aspx.

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INTRODUCTION

The purpose of the Principal Investigator Handbook is to aid researchers in 1) planning, proposing, preparing, funding, executing research studies; and 2) reporting research and program initiatives conducted by the 59th Medical Wing (59 MDW) and overseen by the Office of the Chief Scientist (59 MDW/ST) and the Science and Technology Office (ST) in the San Antonio Military Health System (SAMHS).

Additionally, this handbook serves as a guide for new investigators as well as investigators that are more experienced in their search and submission efforts for other funding opportunities. This guide is not intended to be all-inclusive due to the frequency of program announcements and associated process and policy changes; as such, investigators are encouraged to contact the appropriate office for additional support. The majority of this resource is designed to give the researcher an overview of the strategic emphasis (thrust areas, types of money, research processes, etc.) and a more detailed explanation of areas directly affecting them (e.g., research proposal development, protocol formats, suspense dates, briefings, contracts, etc.). The 59 MDW/ST staff pledges to do all that it can to assist investigators and directors–with the development and execution of proposals, initiatives, projects, and programs.

PURPOSE

All clinical and translational research supported by 59 MDW/ST "irrespective of funding type and source" is overseen by the 59 MDW/ST office. Furthermore, ST supports investigators with identifying funding opportunities to best fit their research focus and proposal. The 59 MDW Chief Scientist has the responsibility to oversee all research involving 59 MDW personnel, in the San Antonio Military Health System (SAMHS) or other sites, as applicable.

Research conducted should address military relevant gaps that apply science and technology to produce solutions to identified needs.

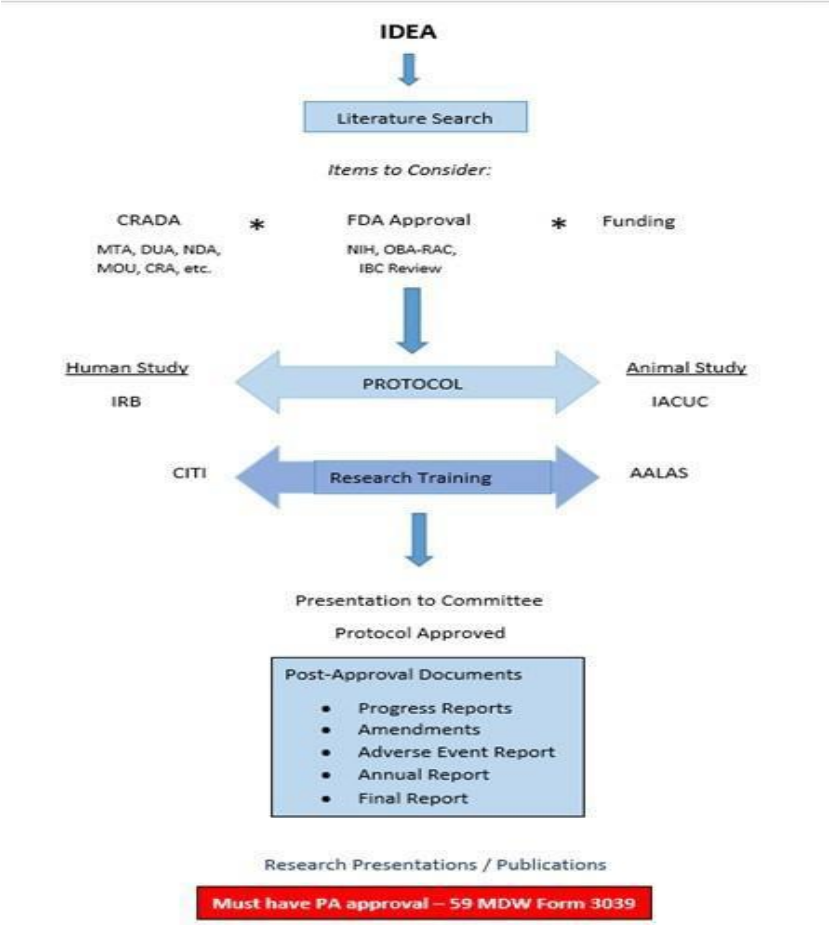
The mission of the 59 MDW/ST is to conduct clinical studies and translational research and apply knowledge gained to enhance performance, protect the force, and advance capabilities across the global health system in support of the Quadruple Aim.

The Chief Scientist provides senior leadership and develops high-level collaborations between Service, Department of Defense, local, national and international government, academia and industry, research, development, test, evaluation and acquisition organizations. The Chief Scientist oversees and manages a dynamic portfolio to meet organizational needs, while leveraging partnerships to develop tailored investments that advance "state of the art" solutions for "world class" precision medical care with an emphasis on mission aligned research in En Route Care, Trauma, Resuscitation and Stabilization; Diagnostics, Therapeutics and 'Omics; Modeling Simulation Training; Clinical Rehabilitative Medicine; and Clinical Investigations. The Wing Chief Scientist is the Institutional Official charged with the responsibility for the protection of human research subjects participating in research, reference, 59th Medical Wing (MDW) Human Research Protection Program.

59th Medical Wing Chief Scientist's Office, Science and Technology (59 MDW/ST) provides scientific, technical, biostatistical, bioinformatics research and regulatory compliance, and program management guidance and support for clinical investigations, studies and translational research conducted by investigators and their collaborators to address unique scientific needs of the 59th Medical Wing, Air Force, Joint community, Department of Defense and the Nation. This specialized expertise enables researchers to exploit new knowledge while developing, evaluating, and integrating applications of innovative technologies to provide the very best patient-centered care from the point of injury in the combat theater to definitive care with the ultimate goal of maintaining and restoring warfighter and beneficiary health, and building warrior medics to address present and future mission challenges. The ST office supports clinical researchers at 70 sites worldwide.

A core function of 59 MDW/ST is to facilitate clinical research to satisfy the knowledge and technology gaps. Consequently, ST has a critical role in the "lifecycle" of all clinical research that is performed within the Chief Scientist's purview. The 59 MDW is a major research execution platform and the largest clinical and translational research activity. ST receives and executes research funds and provides expert assistance to define military-unique capability gaps, identify requirements-

based, and conduct and manage research programs and projects. ST conducts research and facilitates through the acquisition of people and materials to ensure investigators across the 59 MDW and other sites worldwide can complete their research and provide deliverables to fill capability gaps. Additionally, ST assists investigators in obtaining funding of all clinical studies and analyses, basic- to-applied research, advanced development, testing, sustainment, and fielding a product. ST enables best practices, innovation, education, training, translational research, and moving scientific findings to the operational environment and patient care setting.



RESEARCHLIFECYCLE (Figure 1)

Protocol Development

Investigators and the research team are required to comply with the regulatory requirements governing all human and animal research, as applicable to their study. The Research Compliance Office is housed at the 59 MDW/ST CIRS. Research related templates (e.g., research protocols, HIPAA, Informed Consent Document, etc. documents) required to obtain approval for human or animal research are regularly updated and available through the Office of Research Protocol Support either by emailing your request to usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.mil) or through the AFMS Knowledge Exchange: https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx

The 59 MDW Institutional Review Board (IRB) grants approval for research involving human subjects. Approval for animal research studies is granted by the 59 MDW Institutional Animal Care and Use Committee (IACUC). It should be noted in most cases IACUCs are tied to the facility in which the animal use will be conducted. Both the IRB and the IACUC are housed at the CIRS. The Brooke Army Medical Center (BAMC) IRB is housed at the San Antonio Military Medical Center (SAMMC), Department of Clinical Investigations (DCI); and the IACUCs are located at the U.S. Army Institute for Surgical Research and the Tri-Service Research Laboratory at Fort Sam Houston. Additionally, some investigator protocols will go to the U.S. Army Medical Research and Materiel Command (USAMRMC) IRB for review (e.g., protocols with research conducted in-

theater); or to a second level review for IACUC protocols and for greater than minimal risk human studies.

Investigators interested in developing an animal use research protocol should first meet with the Clinical Research Division (CIRS) Laboratory Animal Medical Officer (LAMO) to determine whether the CIRS animal facility can support the appropriate animal model. If the proposed research cannot be accomplished at the CIRS, it may be possible for the LAMO to assist the researcher in locating an alternate animal use facility that can support the research.

The time needed for study approval by the IRB or IACUC can vary depending on the complexity of the study design, specific organizational policies, and/or if a second level review and approval is required. As a result, the 59 MDW/ST highly encourages investigators to initiate this process as soon as possible. The ST staff is committed to helping at every step of the research review process noted above.

Literature Search

A review of literature provides assurance to protocol or funding reviewers that the study is new and innovative. The literature review also provides information on similar studies and methods to improve design of the research study. A literature review should encompass the studies from the three years prior to study submittal and provide from five to ten relevant scholarly citations.

- Support – The 59 MDW Medical Library can provide articles not available on the AF website. For assistance send an email to usaf.jbsa.59-mdw.mbx.wing-medical-library@mail.mil
- A request for additional guidance on, and assistance with, literature reviews can be submitted to the ST Office.

Protocol Narrative

It is important to first develop an outline that includes an overall research question/hypothesis and 2-3 specific aims. This demonstrates to the reviewer how the researcher is going to answer the research question or test the hypothesis. It is critical for specific aims to focus and address gaps in the literature. The background section should reflect commanding knowledge of the topic and existing gaps in the research. The general outline of the background section includes what the problem is and why it's important, the current gold standard to address the problem and the shortfalls associated with it, what you propose to do and why it's better than the gold standard. The objectives and/or hypothesis section is next, followed by the experimental outline. A short paragraph on the military relevance of the research should be anticipated and prepared, as well as a transition strategy. It is good practice to keep a copy of the current research thrust areas when developing the 150-200-word narrative on military relevance. The ST Office employs research scientists that regularly aids in preparing the study design and data analysis sections of the research protocol.

Additionally, research scientists are available to review human subject or animal research protocol before submission to the CIRS. Please note that Food and Drug Administration (FDA) approval is needed for all investigative new drug (IND)/investigative device exemption (IDE) investigations. The ST Office has an on-staff FDA subject matter expert (SME) to assist with research protocols that seek to investigate a new drug or device. Coordination with other service offices may be required (e.g., FDA controlled protocols, clinical investigations, clinical trials, etc.). The ST FDA SME will assist with any necessary coordination.

Training Required to Conduct Research

All research investigators seeking to conduct research involving human subjects are required to complete Collaborative Institutional Training Initiative (CITI) training before submitting their research protocol to the 59 MDW IRB. This training can be easily completed at any workstation where with a ".mil" account. For additional details, please refer to Appendix A.

All research investigators seeking to conduct live animal research or training are required to complete American Association for Laboratory Animal Science (AALAS) Learning Library Training. For additional details, please refer to Appendix A.

For FDA-sponsored IND and IDE studies, PIs are required to complete Good Clinical Practice (GCP) training. GCP training is mandated in the International Conference on Harmonization (ICH) document, "E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6 (R1) Guidance for Industry" accessible at: https://www.fda.gov/media/93884/download

Preliminary Review

All human research protocols are submitted to the Office of Research Protocol Support 4 to 6 weeks prior to the next scheduled monthly IRB meeting. The IRB protocol submission deadlines can be found on the AFMS Knowledge Exchange: https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx.

The investigator can meet with IRB personnel to address any questions or concerns before the monthly IRB meeting. It is at this monthly meeting where protocols are reviewed; approved, conditionally approved pending changes, tabled/deferred, or disapproved. In the case of a deferral or disapproval, we ask that the investigator work with the CIRS staff to address IRB concerns. As always, the ST staff is available to assist with the revision preparation.

All animal research protocols are submitted to the IACUC office 5 weeks prior to the next scheduled monthly IACUC meeting. Within the first 2 weeks following submission, the investigator can meet with CIRS staff for an optional pre-review to address any questions or concerns before the monthly IACUC meeting. It is at the monthly IACUC meeting where the following determinations are made; approval; required modifications to secure approval; or approval is withheld. In the case where an approval is not immediately granted, the ST staff is available to assist with the revision preparation.

59 MDW HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

The 59 MDW Human Research Protection Program (HRPP) exists to protect the rights and welfare of persons who voluntarily participate in research studies conducted by 59 MDW researchers. The conduct of research is deeply connected to the 59 MDW, the Air Force's premier healthcare, medical education and research, and readiness Wing. The 59 MDW is committed to the highest standards of research integrity.

While the protection of human participants is shared among the 59 MDW organizations, each staff member has a role and individual responsibility in the 59 MDW HRPP, the responsibility for the HRPP resides with the 59 MDW Commander. The 59 MDW Commander is the Institutional Officer (IO) recognized by the Air Force Surgeon General's Research Oversight and Compliance Division (AFMRA/SGE-C). Day-to-day IO responsibilities for the protection of human research subjects are delegated to the Authorized Institutional Official (AIO), currently the 59 MDW Chief Scientist and Chief Medical Officer (CMO).

59 MDW Institutional Review Board (IRB)

The mission of the 59 MDW Institutional Review Board (IRB) is to protect the rights and welfare of human research subjects recruited to participant in non-exempt human research protocols at the 59 MDW and other DoD or non-DoD sites in which the 59 MDW IRB is the IRB of Record. The 59 MDW IRB currently makes official determinations regarding whether activities are not research involving human subjects, exempt research involving human subjects, or research involving human subjects requiring IRB approval prior to initiation (32 CFR 219 and DoDI 3216.02_AFI 40-402).

Research Teams

Each member of every research team is responsible for protecting human research subjects. Team members may range from the PI, associate investigators (AI), research assistants, research coordinators, and/or other research staff. Each member of the research team has a strict obligation to:

- Comply with all IRB decisions and organizational requirements.
- Adhere rigorously to the protocol as approved.
- Inform investigators and the IRB of events or unanticipated problems involving risks to research subjects or others.
- Oversee the adequacy of the informed consent process; and
- Take whatever measures are necessary to protect the safety and welfare of research subjects.

Research Subjects

Research Subjects have certain responsibilities as well as rights when participating in a research study:

- Ask questions and seek clarification about the information researchers present to them so that they can make an informed decision about participation.
- Make every reasonable effort to comply with protocol requirements.
- Inform the investigators of any research-related problems or new issues or concerns that might arise, for instance, if they are unable to meet the requirements of participation; and
- Suggest changes to the research or informed consent, where appropriate, to help improve compliance or the subjects' experience.

Ombudsman

Special consideration must be given to the recruitment process for military personnel. In accordance with DoDI 3216.02, when research involves greater than minimal risk, an ombudsman must be employed when conducting group briefings with active duty personnel to ensure they understand that participation is voluntary.

The use of an ombudsman may be recommended in other situations as well, especially when young, enlisted service members are recruited who are trained to follow orders. Service members are trained to act as a unit, so peer pressure should also be considered and minimized if possible.

All Members of the Organization

- To ensure an effective HRPP, all members of the community must promptly report any serious or continuing noncompliance with applicable regulatory requirements or determinations of the IRB of which they become aware, whether they themselves are involved in the research. Individuals may also notify the IRB or HPA directly of any compliance concerns they may have.
- In addition to the responsibilities specifically delegated by the IO, each member of the 59 MDW community plays a role in ensuring the ethical and responsible conduct of human subject research.
- All individuals within 59 MDW have the responsibility to:
    - Promote a research culture that respects and protects research subjects.
    - Maintain awareness of the organizational policies including the definition of Human Research.
    - Consult the Exempt Determination Official when there is uncertainty about whether an activity is Human Research.
    - Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB; and
    - Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the AIO, IRB Administrator.

Helpful IRB Processing Tips

- Engage the Office of Research Protocol Support early in the process to review a checklist of documents needed for the protocol type.
- Allow enough time for consistency and completeness.
- Ensure protocol and ICD information matches exactly (e.g., risks/benefits, study procedures/ methods). Document version control is extremely important.
- Though the IRB Committee is diverse and well-educated both formally and informally, there is the potential they are not familiar with the research being reviewed. Avoid the use of technical or field-specific jargon and acronyms whenever possible. If use of jargon or acronyms is necessary clearly, define each, the first time used.
- Describe in detail the experimental design including all materials and all procedures to be performed. Anticipated research-related procedures should be clearly and sequentially described.
- Explain how the risks are outweighed by the benefits or the risks are reasonable in relation to the benefits; and justify the benefits statement.
- Describe why you chose the sample size proposed. Sample size may be justified by the need to assess variability in the sample or to look for large effects. A power analysis can be determined after meeting with the ST statistician.
- Justify design regarding what conclusions will be drawn (e.g., feasibility, adverse effects, etc.).
- Describe what measures will be taken to prevent, or to minimize the effects of hazards, discomforts, or inconveniences to participants.
- Provide the specifics regarding who will be monitoring the participants, data collection, frequency of monitoring, and provide a clear description of the safety assurances.
- PIs are required to maintain a regulatory file/binder of all approved documents and correspondence from IRB and other regulatory agencies.

Frequently Asked Questions for IRB/IACUC:

What to Expect at the IRB Meeting?

A principal investigator (PI) or representative is invited to the IRB meeting to provide a general overview of their research study to the IRB committee and answer any questions or concerns. This is optional for the PI, but highly encouraged. The board then reviews and votes.

What Happens if I Receive a Conditional Approval Letter?

A study is conditionally approved when specific IRB-directed stipulations and/or changes are required for the protocol. The conditional approval letter is required for a funding award depending on the type of funding requested. The revisions suggested in the IRB conditional approval letter must be completed within 30 days or the study may be administratively withdrawn. IRB-requested changes must be completed in track-change, highlighted or colored text; and returned to the Office of Research Protocol Support for further review by a Designated IRB Reviewer or for review through a fully convened IRB meeting.

The Final Protocol Approval Letter

An IRB final approval letter is granted if the study is approved without changes; and all IRB-directed stipulations and/or changes have been made and submitted to the IRB. Greater than minimal risk studies must go to second-level review prior to approval.

What are IRB Progress Reports?

All researchers are required to provide Annual/Continuing Reviews, and a Final Report upon completion of the study. The final IRB approval letter will note the expiration date of the study and the date your annual report is due. Please note failure to complete and submit required reports may result in suspension or termination of the study. Based on the risk level of the study, it may be necessary to provide reports more frequently than annually.

What to Expect at the IACUC Meeting?

A PI or representative is invited to the IACUC meeting to provide a general overview of their research study to the IACUC and answer any questions or concerns. This is optional for investigators, but highly encouraged. The board then reviews and votes.

What Happens if I Receive a Letter Requiring Modifications to Secure Approval?

A study requiring modifications to secure approval cannot proceed until the modifications are made and reviewed, either by designated reviewers or by full committee review. The modifications must be completed within 90 days in most cases, or the study may be administratively withdrawn. The IACUC-requested changes must be completed in track-change, highlighted or colored text; and returned to the IACUC Office of Research Protocol Support for further review by a Designated Reviewer or for review through a fully convened IACUC**.**

What Are IACUC Progress Reports?

All researchers are required to provide Annual/Continuing Reviews, and a Final Report upon completion of the study. The Final IACUC Approval Letter will note the expiration date of the study and the annual report due date. The IACUC may require reports that are more frequent for certain studies (e.g., following model development animals). Please note failure to complete and submit required reports may result in suspension or termination of the study.

What Are Closeout (Technical) Reports?

All researchers are required to provide a Close-Out Report upon completion of the study. The Closeout Report is due 90 days following study closure. Close-Out Reports are submitted to the study, PI', ST Program Manager. Please note failure to complete and submit required reports may result in missed future funding opportunities. Check with your program manager for the appropriate Closeout (Technical) report format.

Where do I Find Funding for my Study?

The ST Office regularly provides funding source assistance. If you have identified a funding source, the ST employs experts who can assist in preparing budgets, identifying contract labor vehicles for study staffing, and developing the logistics for procuring supplies and/or equipment. For studies that seek extramural (e.g., outside the 59 MDW) collaboration, the ST Office is the point of contact (POC). ST has expertise in coordination of Cooperative Research and Development Agreements (CRADAs) and other research agreements, and interfaces with the Office of Research and Technology Applications (ORTA).

The Final IACUC Protocol Approval Letter

A final approval letter is granted if the study was approved without changes or all IACUC-directed modifications have been made and submitted to the IACUC. Certain protocols must be submitted to AFMRA SGE-C for review and approval prior to implementation (DoDI 3216.01). Protocols are approved for three (3) years contingent upon annual review, after which time, they must be revised and re- submitted.

Principal Investigators and Research Staff Responsibilities

The primary responsibility of PIs and research staff is to safeguard the rights and welfare of research subjects, ensuring subjects' rights and welfare take precedence over the goals and requirements of society and the research. Any questions related to this responsibility or the policies and procedures for protection of human subjects, should be directed to the Clinical Research Administrator or the 59 MDW IRB Chair. To obtain additional information regarding the HRPP, investigators and research staff can visit: https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx.

Financial Conflict of Interest (FCOI)

All researchers, to include research "staff "must disclose a conflict of interest on the protocol template. The conflicted researcher must submit a *Financial Conflict of Interest Disclosure Form* to the COI Manager via encrypted email.

Researchers must also submit the same disclosure form upon any changes to their financial circumstances that may create a research-related conflict. The researcher will send this form by encrypted email to usaf.jbsa.59- mdw.mbx.chief-scientist-hrpp@mail.mil for review and routing to the SES, if necessary. All researchers with a significant conflict of interest will require a COI Management Plan for approval by the 59 MDW IRB and AIO. The 59 MDW IRB will not approve a protocol until a COI

Management Plan is approved by both the IRB and AIO.

Quality Assurance/Quality Improvement

Quality assurance and quality improvement (QA/QI) are the responsibility of the Research Compliance Office. The Research Compliance Officer monitors research involving the use of human subjects approved by the IRB. Activities may include direct audits of study records at the study site, contact with the research sponsor and/or monitoring organizations, contact with other IRBs, interviews with research staff and research participants, and/or review of records within the IRB.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

Research involving animals has extensive requirements that must be met under the requirements of the 59 MDW IACUC. This guide covers the care and use of laboratory animals in DoD programs. All investigators are required to keep protocol binders current with correspondence from the Office of Research Protocol Support, Curricula Vitaes (CVs), AALAS training and certifications, and data collection sheets.

Clinical Investigations and Research Support (CIRS) QUALITY ASSURANCE/QUALITY IMPROVEMENT

Quality assurance and quality improvement (QA/QI) is the responsibility of the Research Compliance Office. The Research Compliance Office ensures quality assurance and quality improvement (QA/QI). They conduct post-approval monitoring research involving the use of animals, which may include direct audits of study records at the study site; contact with the PI; veterinary and/or IACUC observation of animal procedures; interviews with research staff; and/or review of records within the IACUC Office of Research Protocol Support.

Funding

Research funding can be obtained using many different mechanisms. Most often funding is received by the 59 MDW via a Funding Authorization Document (FAD). For funds to be sent to ST the 59 MDW must be designated as a site. The ST Office coordinates with the 59 MDW Resource Management Office (RMO) to ensure the FAD is assigned to the appropriate project.

Once established funding is categorized into Element of Expense Identification Codes (EEIC). Examples of research project categories are travel, supplies, equipment, contracting, and pharmacy. The ST Office will assist the PI in tracking budget execution and providing financial reports to the applicable funding agency. A breakout of funding types received is listed below.

Research, Development, Test, and Evaluation (RDT&E)

Research, Development, Test, and Evaluation (RDT&E) requirements funding is designed for more advanced or complex research projects requiring multi-year funding and is provided by DHP. An RDT&E funding proposal should include contract labor, temporary duty (TDY) expenses, supplies, and equipment. Depending on the specific organization, RDT&E funding is available for multi-year use.

Types of DHP RDT&E Funding		
6.1	Basic Research	Attaining greater knowledge and understanding of fundamental principles of science and medicine.
6.2	Applied Biomedical Research Technology	Refinement of concepts and ideas into potential solutions with a view toward evaluating technical feasibility.
6.3	Medical Technology Development	Development of candidate solutions and components of early prototype systems for test and evaluation, including support of early stage clinical trials.
6.4	Advanced Component Development	Clinical trials for FDA licensed products and accelerated transition of FDA regulated and non-regulated products and medical practice guidelines to operational users through clinical and field validation studies.
6.5	Medical Systems Development	Development of demonstration of medical commodities prior to initial full- rate production and fielding, including initial operational test and evaluation and clinical trials.
6.6	Management Support	Infrastructure and civilian salary support.
6.7	Medical Systems Sustainment Activities	Pre-planned product improvement of fielded medical products and evaluation of the effectiveness of fielded products, therapies, treatments, or medical guidelines.

Operation and Maintenance (O&M)

Operation and Maintenance (O&M) appropriations are used to finance "expenses" not related to military personnel or RDT&E. O&M appropriations are available for obligation for one fiscal year. These proposals are announced in the 3RD or 4TH Quarter and have 4TH Quarter deadlines. These clinical studies promote GHSE/GME involvement and focus on clinical studies.

The above descriptions require interpretation when applying them to DHP funding. For example, under DHP guidelines, it is permissible to use O&M funding for clinical studies of short duration (1 year). O&M funds can also be used for an early operational assessment to determine the maturity of a technology. O&M funding can also be used for feasibility studies to determine if there are technologies that can be used to address certain problems. O&M funds are used for the CIP Intramural Call for Proposals and to award funds for proposals submitted to the Broad Agency Announcement (BAA). Research and Development (R&D) funds are typically used for multi-year programs developing novel capabilities or research that will add to the current body of knowledge.

Procurement

Procurement—also referred to as "Other Procurement/OP"—appropriations are used to finance investment items and to cover all costs necessary to deliver a useful product intended for operational use or inventory. Items classified as investments and financed with Procurement appropriations include those whose system unit cost exceeds $250K. It is unusual for research projects to acquire materials for a project using these types of funds. Funding for large equipment required for a

research study is usually written as part of the budget in the initial funding proposal.

59 MDW Resource Management Office (RMO)

59th MDW Resource Management Office (RMO) can receive R&D, O&M and Procurement funds. If modernization initiatives or projects are awarded, RMO will determine the type of funds appropriate for the initiative or project. The RMO office has Resource Advisors specifically trained with experience in handling these different types of funds. It is important to work with the RMO to clarify verbiage for execution of these funds. RMO will work with the ST Office to move funds to another organization if the initiative or project has a requirement at another facility.

RMO is also able to receive funds provided as gifts and funds use for travel *i*n accordance with MDWI 51-601, individuals conducting research must disclose gifts, including travel, having an aggregate market value of $20 or more per source per occasion, provided that the aggregate market value of individual gifts received from any one person will not exceed **$50** in a calendar year. This exception does not apply to gifts of cash or investment interests (e.g., Stocks, Bonds, Certificates of Deposit).

FUNDING OPPORTUNITIES

Funding awards are categorized as intramural or extramural.

Intramural Awards

Intramural awards derived from announcements for research funding have specific requirements. The announcements are available throughout the year. More information on the latest research funding opportunities can be found by contacting the ST Office and at http://www.grants.gov, http://grants.nih.gov; http://www.arl.army.mil; beta.SAM.gov ; and http://cdmrp.army.mil.

CIRS (CIP) Baseline GME/GHSE Intramural Funding

Program 8 (O&M) – One-year money to support resident/fellow research. Can be used to purchase supplies and in some cases equipment. Cannot be used to purchase manpower or travel.

Note: Types of Intramural Award

- Program 8 (O&M) – Award has less than 1-year execution and with average about $200K.

Defense Medical Research and Development Program (DMRDP)

As directed by the Office of the Assistant Secretary of Defense for Health Affairs [OASD (HA)], the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Development Command (USAMRDC) Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) execution management support for the six DHP core research program areas listed below. Each of these major research program areas are strategically guided by a committee, called a Joint Program Committee, or JPC, which consists of DoD and non-DoD medical and military technical experts. These experts work through coordinated efforts to translate guidance into research and development needs. They also have key responsibilities for making funding recommendations and providing program management support. Within the USAMRMC, operational support for the JPCs is provided by multiple execution agents, including the CDMRP, individual laboratories, and advanced developers. CDMRP provides program and award management support primarily for basic through translational research (Program Elements 6.1 through 6.3) and works closely with the JPCs to transition products to advanced development. For additional details, visit https://cdmrp.army.mil/dmrdp/default.

- JPC1 – Medical Simulation and Information Sciences Research Program
- JPC2 – Military Infectious Diseases Research Program
- JPC5 – Military Operational Medicine Research Program
- JPC6 – Combat Casualty Care Research Program

- JPC7 – Radiation Health Effects Research Program
- JPC8 – Clinical & Rehabilitative Medicine Research Program

Congressionally Directed Medical Research Program (CDMRP)

The CDMRP originated in 1992 via a Congressional appropriation to foster novel approaches to biomedical research in response to the expressed needs of its stakeholders, the American public, the military, and Congress.

The CDMRP fills research gaps by funding high impact, high risk and high gain projects that other agencies may not venture to fund. While individual programs are unique in their focus, all of the programs managed by the CDMRP share the common goal of advancing paradigm shifting research, solutions that will lead to cures or improvements in patient care, or breakthrough technologies and resources for clinical benefit. The CDMRP strives to transform healthcare for Service Members and the American public through innovative and impactful research. For more information on CDMRP and funding opportunities visit https://cdmrp.army.mil/default.

Extramural Awards

National Institute for Health (NIH) Multi-Institutional Announcement(s)

- This type of study may include DoD facility as collaborators only, not primary submitters.

U.S. Army Medical Research and Development Command's (USAMRDC) Broad Agency Announcement (BAA)

- The USAMRDC BAA is continuously open. The purpose of the announcement is to enrich both military and civilian medical practice and knowledge. The BAA considers solicitations from national, international, for-profit, non-profit, public, and private organizations.

711th Human Performance Wing Broad Agency Announcement BAA)

- The Air Force Research Laboratory, 711th Human Performance Wing (711 HPW) BAA is open for limited time.

Tri-Service Nursing Research Program (TSNRP)

- This award supports rigorous scientific research studies and evidence-based practice projects in the field of military nursing. It is the only program that focuses exclusively on research in this field.
- TSNRP offers awards for nurses at all stages of their careers. Grant applicants may be: Active duty, Reserve or retired; military nurses from the United States Army, Navy or Air Force; or National Guard Nurse Corps Officers. For more information visit https://www.usuhs.edu/tsnrp/ mission.
- Research awards include:
    - Graduate Research Award
    - Novice Investigator Award
    - Exploratory Research Award
    - Career Development Award
    - Investigator-Initiated Award
    -
- The evidence-based practice awards are the:
    - Graduate Evidence-Based Practice Award
    - Conceptual Guideline Development Evidence-Based Practice Award
    - Implementation of Innovation Evidence-Based Practice Award

Other

- Many other current calls for proposals from federal agencies can be found at www.grants.gov. See Appendix B, ST Policy letter on applying for grants via online grant submission sites.

RESEARCH PROPOSAL

All funding applications require a research proposal; in some instances, an IRB approved research protocol. The award announcement identifies specific guidelines for submission. All submissions will vary in length, format and information needed. Follow the instructions carefully for a complete submission and to ensure grantor review.

The Pre-Proposal Submission

The pre-proposal usually is a condensed version of a full proposal for the funding reviewers to select research projects that best fit identified gaps. Documents to be included in the submission vary depending upon the announcement. A white paper is usually required and will condense the background, military relevance, hypothesis/research question, aims, methods, references, and deliverables of the study. The cost proposal needs to address funding needed for personnel, equipment, supplies, and travel. In addition, a QUAD chart is typically required. A QUAD chart is a single PowerPoint slide divided into 4 sections. These sections vary, but usually include title, investigator, background, military relevance, overall budget, picture, and deliverables. The ST Office can provide a QUAD chart template.

Selection for Full Proposal

Pre-proposals are competitively reviewed prior to selection to go through the full proposal process. A full proposal should carefully follow the guidelines identified in the program announcement. Items required may include the following (please see the ST Research Cell for the current template):

- Abstract
- Background
- Military Relevance
- Technical Program Summary/Methods
- References
- Milestones/Deliverables
- Facilities/Equipment/Experience
- Subcontracts
- Cost proposal (see below budget)
- Bio sketch of Investigator and Co-Investigator
- Letter of Support
- QUAD Chart

Budget Development for Research Proposal Labor:

The first step is to determine the service contract labor standards. A Performance Work Statement (PWS) describes the type of work required. Also required is the Contract Data Requirements List (CDRL), this includes the deliverables that will be submitted to the funding agency (e.g., final reports, interim reports, data packages, etc.) from the contractor. The ST Budget Analyst will assist with finalizing the package and coordinating the funding with a contracting route. If the acquisition route is using a contracting office, the request will be advertised to the contractors for 14 days, at which time, each contractor who wants to bid will submit a proposal. A grant or cooperative agreement requires a Statement of Work (SOW). The ST Office can provide an example.

Common Research Labor Categories

Research Nurse Coordinator Research Assistant Clinical Research Scientist Epidemiologist Statistician Veterinary/Surgical Technician Project Manager

Supplies and Equipment (Medical):

A list of research project supplies and equipment should be drafted by using vendor quotes. Overhead charges may apply; the ST Office is able to assist with the totals for each organization. Once funding has been received, a Project Funds Management

Record (PFMR) letter will allow access for a research member to order supplies from the established MEDLOG account through the Defense Medical Logistics Supply System (DMLSS). The estimated time for an account to be established is 4-6 weeks. Once the account is established, supplies and equipment (up to $3K) may be ordered. If an item exceeds $3K, the item will be purchased through contracting. A Form-9 and Sole Source Justification may be required for the procurement action/purchase. The ST Office will assist with the required documents.

Equipment (non-Medical):

There are three methods for ordering non-medical equipment: Government credit card, Form-9, and contract.

Travel (TDY):

ST will provide the travel cost estimate (investigator must provide the date of the conference/training, location, number of people traveling, conference fees). ***NOTE:*** Travel ***must*** be completed within the same years as the funding for O&M funded projects. RDT&E funded projects allow for project related travel to occur during the length of the project. Each funding announcement contains specific travel funding requirements. If you have any questions, the ST Research Cell can provide a template for travel.

Facility Fee:

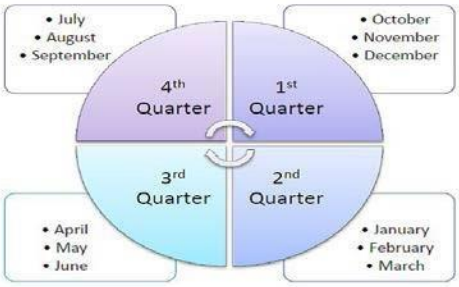
Facilities such as the U.S. Army Institute for Surgical Research (USAISR), Navy Medical Research Unit (NAMRU) and universities have additional overhead or laboratory fees that also must be figured into the project total costs. The ST Office can assist with adding these fees into the research budget.

REPORTS AND REVIEWS

Technical and financial reports are required quarterly, annually and research study closure. For funded projects, the ST Office will assist with the quarterly report and other requested reports. For DMRDP funded projects, the JPC representative will contact the PI or external collaborator directly and the PI is to coordinate with the assigned ST Project Manager. The DMRDP will normally send the format along with report requirements and instructions. There is also an annual Research Program Review conducted by the 59 MDW Chief Scientist to assess scientific and programmatic progress. This review will include higher level representation, and Major Command (MAJCOM) Surgeon representatives. These reviews provide an in-depth overview of the Wing and the research portfolio to baseline programs and assess progress on addressing military relevant capability gaps. These reviews are critical in preparing reviews to the DHA Research and Development Directorate and the Defense Medical Research and Development Program. ST will coordinate the format and suspense requirements with the PI. A kick-off meeting will be held with ST staff, the PI and research team prior to project initiation to introduce reporting requirements. Check with Program Manager for reporting requirements and formats.

Quarterly Reports

Quarterly reports are required once a program/initiative is started.



59 MDW/ST Quarterly Progress Update Reports (QPUR):

The QPUR is to update the funding organization on current status of cost, schedule and performance.

CDMRP/JPC Technical Reporting Requirements:

The majority of JPC funded studies have an extramural collaborator, who is ic ıe extramural collaborator or recipient is awarded a cooperative agreement by the U.S. Army Medical Research and Development Command (USAMRDC). These agreement awards have special terms and conditions clauses to include the technical reporting requirements.

Intramural Quarterly Reporting Requirements:

Quarterly reports are required to update the funding agency on status of the project, budget and research presentations and publications. At the initial notification of award, the organization will provide a template for the quarterly report. The ST Office can assist the GME or investigator with these quarterly reports. To facilitate the reporting, please provide copies of abstracts, journal articles, book chapters or any publications to your Project Manager (PjM) at the time of publication acceptance.

Clinical Investigations Program (CIP) Quarterly Updates:
The 59 MDW CIP collates data on 59 MDW medical research writings and oral presentations prepared by personnel assigned to the Wing on a quarterly basis. The report includes program accomplishments and significant events, significant studies, presentations, and publications. GME/GHSE will be contacted by CIRS staff if information is required for the quarterly report. Additionally, these research writings and presentations are uploaded to Defense Technical Information Center (DTIC) on a regular basis. Refer to 59 MDWI 41-108 for more information.

Other Reports: Annual and Close-Out/End of Project Reports_Annual Protocol Reports:

These are IRB and IACUC required documents. An Annual Protocol report template is provided by the Office of Research Protocol Support or the IACUC Office of Research Protocol Support. The purpose of the report is to summarize the research completed that year as requested in each section of the template.

Protocol Final Reports:
These are IRB and IACUC required documents. A protocol final report is required by the IRB and IACUC. The purpose of the report is to summarize the research performed over the duration of the study to finalize the close of the study.

Project Final Reports – Technical and Programmatic:
A report is required to be submitted in DTIC. The ST Office will assist investigators in the preparation of this report. All documentation on DTIC requires a Public Affairs determination for approval.
Contact the CIRS for 59 MDW Form 3039 requirements to obtain Public Affairs approval. CIRS will submit your cleared report into DTIC. Refer to 59 MDWI 41-108 for more information.

FOOD AND DRUG ADMINISTRATION (FDA)

The FDA is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, as well as all medical devices. As the regulatory agency the FDA is responsible for determining the appropriate regulatory pathway for any medical product: these pathways can include New Drug Applications (NDAs) which includes biologics, Investigational New Drugs (INDs), Investigative Device Exemptions (IDEs) and medical device clearances including De Novo and Pre-Market Notification (510k). So, if a research protocol includes one of these drugs or devices OR a drug or device that is already on the market is being used in a new way in the research, an assessment of regulatory requirements should be performed.

FDA Regulated Medical Products of Concern to the Air Force:
1. Drugs, including prescription drugs and Over-the-Counter (OTC) drugs; 2. Medical Devices, including simple items such as tongue depressors or crutches, complex technologies such as pacemakers or imaging technologies, dental devices and implants/prosthetics; 3. Biologics, includes vaccines, blood and blood products, cellular/gene therapies, tissue or tissue products and allergenics, and 4. Combination Products, which is a product comprised of two or more regulated components, such as a medical device and drug.

The FDA requirements for medical products research is varied based on how the medical product fits within the definitions above, the intended/indications for use, and the stage of the research. All PI's working or proposing projects should contact the subject matter expert in the ST Research Cell for an evaluation of potential regulatory requirements. If the research involves and outside entity whether it be a drug developer or other commercial interest, an academic partner or another government agency: the ST office can assist in the development of a regulatory assessment AND provide guidance for what regulations are applicable and how to comply with those regulations. If the research does involve other partners, please see the section below on Research Agreements for assistance in developing these relationships according to DoD and Air Force Regulations.

RESEARCH AGREEMENTS/TECHNOLOGY TRANSFER (ORTA REVIEW)

The 59 MDW/ST Office of Research and Technology Applications (ORTA) plays a key role in shaping the 59 MDW's approach to technology transfer by developing and promoting the partnerships necessary for technology transfer (15 USC 3710). 59 MDW federal scientists and their academic/industry partners see ORTA as the first stop in initiating their technology transfer efforts. Patent applications and licensing, Cooperative Research and Development Agreements (CRADAs), technology

assessments, state and local technology transfer programs are just some of the areas where ORTA is actively involved.

As representatives of 59 MDW/ST ORTA, Technology Transfer Specialists/Consultants serve as brokers, connecting the people essential for the effective transfer of technology. While technology transfer does have technical components, it is also dependent on person-to-person relationships forged inside and outside of the laboratory (i.e., Center of Excellence, department or clinic). Having a greater understanding of not only the function of the ORTA but also of technology transfer issues in general, will make our efforts encouraging your laboratory's participation in technology transfer that much more effective.
This information is intended to provide internal and external audiences with information to determine if technology transfer is appropriate to address your research and technology objectives. The processes described below apply to standard, unclassified Technology Transfer (T2) agreements. Nonstandard agreements involve classified, Military Critical Technologies, Foreign Owned Controlling Interest (FOCI), technology brokers, and Small Business Innovation.

ORTA ensures researchers make the most of collaborations with non-AF entities. ORTA promotes T2, the transfer and/or exchange of knowledge, capabilities, or technology with industry, state and local governments, academia and other federal agencies to fulfill both military needs and actual or potential public or domestic needs.

Researchers should contact the 59th MDW/ST ORTA as early as possible in the process of collaborating with a non-AF entity in research that may require Cooperative Research and Development Agreements (CRADA), Material Transfer Agreements (MTA), Education Partnership Agreements (EPA) or other technology transfer vehicles.

To discuss technology transfer requirements, contact the 59 MDW/ST ORTA, Technology Transfer (T2), email: usaf.jbsa.59-mdw.mbx.59-mdw-st-technology-transfer-office@mail.mil, or phone: (210) 292-1019, (210) 292-3546

TYPES OF AGREEMENTS

Cooperative Research and Development Agreement (CRADA):
A CRADA is a legal agreement between a federal agency 59 MDW and one or more non-federal parties, such as private industry and academia, to collaborate on research and development. While no federal funding is authorized for a CRADA, CRADA's are key technology transfer mechanisms for removing barriers to collaboration, obtaining long-term value, and high returns on R&D investments. Additionally, CRADA's can allow the transfer of funds from a non-federal entity to a federal entity. The end objective of a CRADA is to advance science and technology that meets Air Force mission requirements and has the potential for commercial applications.

While the CRADA process will likely be the T2 mechanism for most purposes, there are other technology transfer mechanisms available depending on the situation. These include:

Non-Disclosure Agreement (NDA):
Protects proprietary information exchanged between parties during initial interactions and discussions between the 59 MDW and another party on specific technical areas.

Memorandum of Understanding (MOU):
Non-binding document signed by parties interested in pursuing a comprehensive agreement for the transfer of technology that defines specific technical areas of interest and the ground rules for interaction and discussion between the parties.

Patent License Agreements:
A grant of permission by USAF for commercial or noncommercial use of 59 MDW developed intellectual property. Licensee pays maintenance fees, and royalties on sales. The U.S. government has a nonexclusive, nontransferable, irrevocable, paid-up, worldwide license to practice or have practiced 59 MDW developed or joint developed inventions.

Material Transfer Agreement (MTA):
An MTA is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes.

Commercial Test Agreements (CTA's):

Permits outside users from industry, universities, and other governmental agencies to conduct research using the 59 MDW's unique experimental research equipment, facilities or other testing facility for the testing of materials, equipment, models, computer software, and other items.

Education Partnership Agreement (EPA):

It is a formal agreement between a defense laboratory and an educational institution to transfer and/or enhance technology applications and provide technology assistance for all levels of education (pre-kindergarten and up).

Partnership Intermediary Agreement (PIA):

PIAs allow federal research agencies to enter into an agreement with a non- profit organization, state or local government (partnership intermediary) to assist the federal agency with its technology transfer efforts. PIAs help find outside industry/academia and inter-service/interagency mission enhancing partnerships, provide access to and assist companies in technology transfer, help small businesses, and work hard for the directorates with difficult to transfer military specific technologies.

Conferences, Symposia, Exhibits:

Represent opportunities to discuss and try to find solutions to common issues that arise in other ORTA program's daily implementation of Technology Transfer strategies. The team also participates in technical programs such as workshops, forums, and symposia, in order to collaborate with partners outside the USAF community.

Technical Assistance and Assessments:

ORTA specialists/consultants prepare application assessments for selected research and development projects in which that laboratory is engaged and which in the opinion of the laboratory personnel may have potential commercial applications.

'Personnel Exchange', 'Use of facilities' (either at WHASC or industry/academic partner) and '**Technical Data Exchange'** are other technology transfer mechanisms available depending on the situation.

59 MDW/ST ORTA can help you determine which is right for you. Meet with them early in your research process.

Are Proprietary Ideas Protected?

Yes. At the conclusion of the cooperative effort, the results may often be considered proprietary. All parties agree to keep the research results confidential to the extent permitted by the law until they are published in scientific literature or presented at a public forum. The private industry cooperator can retain patent and intellectual property rights or retain an exclusive license to a patent. The government has the right to use any information; however, must respect the proprietary rights of the cooperator. In addition, any other government agency may use the information emerging from a CRADA effort, but it must also protect the cooperator's proprietary rights. The proprietary right protection gives added incentive to the cooperator for transferring the technology or research development through marketing and commercialization efforts.

Securing Intellectual Property (Why and How to File a Patent)

While conducting official duties, Air Force personnel may generate patentable ideas, processes, and inventions that must be secured prior to disclosure to the public. This is especially true in research, development, and clinical practice. As such, Air Force personnel are directed by AFI 51-303 (paragraph 2.1.2.) to address this possibility before publicly disclosing the idea(s) or any related details, which includes publishing results of research in journals, periodicals, and abstracts for conferences. To initiate a review of potentially patentable ideas, processes, and inventions, send an email with the background information to the Office of Research and Technology Applications (ORTA) who will assist in the completion and filing on the AF Form 1279 Disclosure and Recording of Invention and the accompanying AF Form 1981 Invention Evaluation which includes the inventor's supervisor recommendation for filing a patent. Once patented, the patent will be advertised to the medical industry community for consideration of licensing. If a company licenses the patent, the company will develop the medical product or process and sell to industry and the military. The licensing and profit from sales may result in royalty payments back to the inventor(s). Overall, the creation of a patent creates intrinsic value of the ideas, as a company is more likely to invest in developing and selling a product that other companies cannot develop or profit from (exclusive rights), and the government benefits from industry investing funding and providing a product quickly

and affordably with minimal government funding.

TRANSITION STRATEGIES

Transition Strategy (ies): The main element of a knowledge or technology transition agreement is the transition strategy. The transition strategy is essentially a short narrative "map" on how the results generated from the research and development project will be applied or used. The perspective used/presented should be that the research and development activity will be successful and can even state "if successful" as a caveat to applying the results and outcomes. The transition strategy should reference the starting and ending technology or knowledge reference levels following the guidance in 59 MDW/ST KRL/KTA TRL/TTA 10 October 2019 policy memo (Appendix C). The transition strategy should identify the population being supported by the research and development effort and the operation/function mission(s) affected. Most important is to clearly define the list of deliverables that will be generated, and as a minimum must include a report that is shared with 1) the representative(s) of the end users/customers, 2) any decision maker(s) for providing support and applying the results/fielding the capabilities to include DHA and JPCs, 3) with other military research organizations or committees (i.e.: Navy, Army, VA, CoTCCC, etc..), submitted to DTIC and/or other medical data repositories, and presented as an abstract at MHSRS or other conferences, symposiums, etc. May also include submission to a peer-reviewed journal.

Other deliverables may include but not limited to (if applicable):

- Report for end-user representatives to answer end-users' questions with recommendations for decision makers, especially for applying the information gathered/generated by the research
- A draft of a recommended treatment strategy that may be followed by an attending physician to apply the knowledge to practice, even if the proposed use is off label (must state so)
- An outline for a follow-on study, a draft study plan, or a full study proposal that addresses how to mature the state of the science of the research topic from one knowledge readiness level to the next, or builds a sufficient case to transition the knowledge to clinical practice (revision to existing or generation of a new Clinical Practice Guideline or CPG)
- A statement of the type and number of clinical trial(s) that may be required, and the types and estimate of the number of patients that would be enrolled; can base the estimated types and numbers from similar clinical studies
- If a change of a Clinical Practice Guideline (CPG) is proposed, identify how the change would be submitted, reviewed, accepted, and published (if successful); clearly identify who the decision maker is or will be for the associated CPG.
- One transition deliverable could be the initiation of an Evidence Based Practice (EBP) review that will assess if the available knowledge (KRL) is sufficient to warrant a change in practice (a modified or new CPG, or a memo from DHA directing the application of the new or modified practice in the DoD)
- A statement that all intellectual property (knowledge) generated will be reviewed by the ORTA to determine if intellectual property warrants the submission of a patent disclosure package application to legal
- A statement that the data will be provided to a company through an established collaborative research agreement so that they can file a package with the FDA to seek a new/expanded label indication for an approved medical product or file Premarket Approval (PMA) package to the FDA to obtain clearance/approval for a new medical product (a path forward)
- One of the results (deliverables) for early research (6.2) can be an enhanced/refined knowledge/technology transition strategy or agreement (KTA/TTA) for signature.

Providing more details helps reduce the uncertainty and improves the transition potential. The key is to convey to the reviewers that the PI/researcher understands what it would take to apply the results to practice and conveys this understanding (i.e.: strategy) in the project proposal/plan.

Example of poorly written transition strategy:

Transition Plan/Deliverable(s): The deliverables of the current proposal will be both academic and programmatic to

improving health care in the field. The outcome of the current study will provide the foundation for initiating other studies to move the novel therapeutic being investigated towards human use and FDA approval. The academic products will be presented at high impact, military relevant scientific meetings and submitted to peer reviewed publications. *Note: No mention of the Knowledge Readiness Level (KRL), how it will be increased, and from what level to what level. No mention of the end-user(s) who would benefit from this research project, what deliverables will be, how the knowledge will be provided (reports!) and applied (provided to decision makers), no references to clinical operations/processes/associated CPGs, and more.* For additional details, please refer to Appendix C.

RESEARCH CONFERENCES

Before you travel:

- All presentation materials (poster, briefings etc.) must be approved in accordance with 59 MDWI 41-108, Presentation and Publication of Medical and Technical Papers, using the AF Form 3039. This approval process can take up to 30 days.
- Funding for conference travel, see specific conference information listed below. All funding must be approved by your chain of command.
- If travel is gifted (proffered) please refer to 59 MDWI 51-601, Management of Gifts and Grants of Tangible Property. This approval process can up to 30 days.
- Provide a copy of all materials and trip reports to 59 MDW/ST.

Military Health System Research Symposium (MHSRS)

The Military Health System Research Symposium (MHSRS) is the Tri-Service symposium which incorporates ATACCC, AFMS, and Navy Medicine Research Conference. This symposium is co-sponsored by the DMRDP and JPC 6, Combat Casualty Care Research Program. It is the premier DoD scientific meeting to address the unique medical needs of the warfighter and a collaborative environment for military medical care providers with deployment experience, DoD scientists, academia, and the industry. Presenters and attendees discuss and present the advancements of research and healthcare development in areas of Combat Casualty Care, Military Operational Medicine, Clinical and Rehabilitative Medicine, and Military Infectious Disease Research Programs. The aim is to optimize care for members of the Uniformed Services in operational settings. The MHSRS is held annually in August, investigators receiving AFMS funds are required to submit an abstract for presentation. The ST Office is available for assistance with abstract submissions. Additional MHSRS information is available at https://mhsrs.amedd.army.mil/SitePages/Home.aspx.

Research Fundamentals Workshop

The Research Fundamentals Workshop is a biannual symposium available to all GME students. While residents have priority for attendance, the Research Fundamentals Workshop is open to all health care professionals. This venue provides an overview of local research activities-presentations and posters- and offers basic and advanced sessions on protocol and proposal preparation.

SAMHS and Universities Research Forum (SURF)

SURF is an annual local symposium and collaboration between University of Texas-San Antonio, University of Texas Health Science Center at San Antonio and the San Antonio Military Health System. This venue provides an overview of both collaborative research efforts as well as institutional projects. This is an excellent forum for networking with regional experts with a variety of clinical and non- clinical backgrounds.

Science and Technology Research Support

Orientation:
When a research protocol is approved and prior to funding being released, ST staff will conduct a meeting with each PI.

IACUC/IRB:
The ST Office can assist with protocol development prior to submitting for a funding opportunity. All funding requires an approved IRB/IACUC protocol.

Performance Work Statement (PWS):
A PWS is required to obtain personnel for a funded research study. An example PWS is available in the ST Office.

Statement of Work (SOW):
Required for grant/cooperative agreements (assistance to academia or industry) or a contract that the government receives a product.

Supplies and Equipment:
Complete a cost estimate including a list of supplies and equipment with vendor quotes, sources, total costs (including shipping and maintenance plans if applicable when purchasing equipment). A surcharge may apply when ordering supplies and equipment. The amount varies depending upon which organization submits the order.

Information Management/Information Technology (IM/IT):
A cost estimate including a list of all required computer hardware and software with vender quotes, sources, total costs (including shipping and license fees), and any plans (if applicable for equipment) will be submitted for purchase. Reports: Technical and financial reports are required quarterly and annually. ST is available to assist with templates and completion of the reports: 59 MDW/ST funded projects – ST Office submits quarterly reports to AFMRA/SG5 in coordination with the PI and requires semi-annual and annual reports from the PI.

- DMRDP funded projects: PI or Foundation submits the quarterly reports.
- Additional reviews and/or approvals may be required if the research involves using or developing IT systems or software applications not currently approved by Defense Information Systems Agency of DHA, please coordinate with your IT Department and HIPAA Office.

Budget Management:
When crafting a research proposal for funding, please consult with the ST staff for all costs related to your project to ensure the most accurate cost estimates for proper funding. *Labor, Equipment, Supplies*, and *Travel* should all be incorporated in the research budget.

Contracting:
Investigators need contracts if labor or equipment is to be purchased. The ST staff has expertise in assisting the PI with drafting the appropriate documents and providing follow up on items requested.

Letter of Support:

For additional details, please refer to Appendix D.

PROGRAM MANAGEMENT REVIEW (PMR):

The Program Management Review (PMR) provides the Chief Scientist with programmatic (cost, schedule, performance) analysis and project scientific merit at least once a year. The PI will work with the assigned 59 MDW/ST Program Manager through-out the duration of the research study. The PM will assist the PI with documentation needed for the PMR. The PI presents their project at the PMR and answers questions related to the research study. A pre-PMR is optional for the ST Office to gather correct information for the annual review.

Helpful Tips and Phone Numbers

59 MDW Chief Scientist /ST Main Office (210) 292-2097 (DSN 554)
Email: usaf.jbsa.59-mdw.mbx.59-mdw-st@mail.mil

Prior to protocol development, contact with the following individuals at the appropriate JBSA office (depending on where your research will be conducted) is encouraged for assistance in protocol design/ methods, obtain protocol and to review the need for agreements (i.e., data use agreements):

59 MDW Clinical Investigations and Research Support - (210) 292-2922 (59 MDW/ST/SGVU)
59 MDW Clinical Investigations and Research Support IRB - (210) 292-5203 (59 MDW/ST/SGVU)
To obtain current protocol forms and templates:
https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx

SAMMC Dept. of Clinical Investigations IRB – (210) 916-2598 (MCSR-CL)
U.S. Army Medical Research and Material Command (USAMRMC) IRB – (301) 619-7801 (MCMR-RPI)

59 MDW Clinical Investigations and Research Support IACUC - (210) 292-7295 (59 MDW/ST/SGVU)
To obtain current protocol forms and templates:
https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx

Tri-Service Research Laboratory (TSRL) IACUC – (210) 539-7301 (711HPW-RHDV)
USAISR IACUC - 210-539-9528 (MCMR-SRR)

To check on Protocol Status or ask questions pertaining to your protocol
59 MDW Protocol Office (210) 292-4012/2977, email protocol documents to
usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.mil

SAMMC Protocol Office (210) 916-2598, email protocol documents
usarmy.jbsa.medcom-bamc.mbx.bamc-irb@mail.mil or provide via CD.
TSRL Protocol Office: NAMRU (210) 539-7045, 711 HPW IACUC (210) 539-7301
USAISR/MRMC Protocol Office (210) -539-4366

Research/Protocol Compliance Office POCs, depending on where your research will be conducted:

59 MDW Clinical Investigations and Research Support Quality Assurance (QA)/Quality Improvement (QI) POC – (210) 292-5146
SAMMC QA/QI POC – (210) 916-2000 or (210) 916-9425
USAISR/ TSRL QA/QI POC – (210) 539-4366
U.S. Army Medical Research and Material Command (USAMRMC) QA/QI POC – (301) 619-7550 (DSN 343)

59 MDW ST Technology Transfer Office (ORTA), email: usaf.jbsa.59-mdw.mbx.59-mdw-st-technology- transfer-office@mail.mil

Helpful Web Links

Defense Health Agency and Military Health System (https://health.mil/dha)

59 MDW Science & Technology- AFMS Knowledge Exchange Homepage (CAC)
(https://kx.health.mil/kj/kx8/59MDWScienceAndTechnology/Pages/home.aspx)

59 MDW Science & Technology – 59 MDW SharePoint page (CAC) (https://59 MDW.samhs.health.mil/science-technology/SitePages/Home.aspx)

59 MDW Science & Technology-public webpage
(https://www.59 MDW.af.mil/Units/Chief-Scientist-ST/)

59 MDW HRPP Operating Instructions (CAC)
(https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/Human-Research-Protection- Program-Operating-Instructions.aspx)

59 MDW HRPP- public webpage
(http://www.59 MDW.af.mil/Units/ChiefScientist- ST/HumanResearchProtectionProgram.aspx)

59 MDW Clinical Research Division- AFMS Knowledge Exchange Homepage (CAC)
(https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx)

59 MDW Science and Technology Organizational Mailboxes
59 MDW Mailbox 59 MDW ST
usaf.jbsa.59-mdw.mbx.59-mdw-st@mail.mil
59 MDW Mailbox Chief Scientist HRPP
usaf.jbsa.59-mdw.mbx.chief-scientist-hrpp@mail.mil
59 MDW Mailbox Wing Clinical Research
usaf.jbsa.59-mdw.mbx.wing-clinical- research@mail.mil
59 MDW Mailbox Wing CIRS Protocol
usaf.jbsa.59-mdw.mbx.wing-crd- protocol@mail.mil
59 MDW Mailbox CIRS Publications and Presentations
usaf.jbsa.59-mdw.mbx.crd- publications-and-presentations@mail.mil
59 MDW Mailbox 59 MDW ST Technology Transfer Office
usaf.jbsa.59- mdw.mbx.59-mdw-st-technology-transfer-office@mail.mil

Feedback Survey Links
59 MDW ST Customer Feedback Survey (2019)
https://www.surveymonkey.com/r/ZZPW7Y5

59 MDW HRPP/COI Newcomer's Feedback Survey
https://www.surveymonkey.com/r/Z3NBXLZ

59 MDW Office of Clinical Research Support
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COMMONLY USED ACRONYMS

59 MDW	59 Medical Wing
AALAS	American Association for Laboratory Animal Science
AAALAC	Association for Assessment of Laboratory Animal Care
AE	Adverse Event
AFMS	Air Force Medical Service
AFMRA	Air Force Medical Readiness Agency
AI	Associate Investigator
AIO	Authorized Institutional Official
BAA	Broad Area Announcement
BAMC	Brooke Army Medical Center
CDMRP	Congressional Directed Medical Research Program
CITI	Collaborative Institutional Training Initiative
CIP	Clinical Investigation Program
COI	Conflict of Interest
COR	Contracting Officer Representative
CPG	Clinical Practice Guide
CRADA	Cooperative Research and Development Agreement
CIRS	Clinical Investigation and Research Support
DCI	Department of Clinical Research
DHA	Defense Health Agency
DHP	Defense Health Program
DMLSS	Defense Medical Logistics Supply System
DMRDP	Defense Medical Research and Development Program
DSMB	Data Safety Monitoring Board
DTIC	Defense Technical Information Center
DUA	Data Use Agreement
FAD	Funding Authorization Document
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GHSE	Graduate Health Sciences Education
GME	Graduate Medical Education
HQ	Headquarters
HRPP	Human Research Protections Program
HUD	Humanitarian Use Device
IACUC	Institutional Animal Care and Use Committee
IM/IT	Information Management / Information Technology
IND	Investigational New Drug
IO	Institutional Official
IRB	Institutional Review Board
ISR	U.S. Army Institute of Surgical Research
JPC	Joint Program Committee
MPPG	Medical Planning and Programming Guidance
MTA	Material Transfer Agreement
NAMRU	Naval Medical Research Unit
NIH	National Institute of Health
O&M	Operation and Maintenance
OASD/HA	Office of Assistant Secretary of Defense Health Affairs
ORTA	Office of Research and Technology Applications

PFMR	Project Funds Management Records
PI	Principal Investigator
PM	Project Manager
PMR	Project Management Review
PWS	Performance Work Statement
QA/QI	Quality Assurance/Quality Improvements
QPUR	Quarterly Progress Update Report
R&D	Research and Development
RDT&E	Research, Development, Test and Evaluation
RMO	Resource Management Office
SAE	Serious Adverse Event
SAMHS	San Antonio Military Health System
SAMMC	San Antonio Military Medical Center
SG5	Research and Acquisition Directorate
SBIR	Small Business Innovation Research
SOW	Statement of Work
ST	Science and Technology
STTR	Small Business Technology Transfer
T2	Technology Transfer
TDY	Temporary Duty (i.e., Travel)
USAMMDA	U.S. Army Medical Material Development Activity
USAMRDC	U.S. Army Medical Research and Development Command
WHASC	Wilford Hall Ambulatory Surgical Center

DEFINITIONS

Adverse Event: An adverse event (also referred to as an adverse experience) can be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug and does not imply any judgment about causality. An adverse event can arise with any use of the drug (e.g. off-label use, use in combination with another drug) and with any route of administration, formulation, or dose, including an overdose.

Assent: Agreement to participate in proposed research, given by an individual not competent to give legally valid informed consent (e.g. a child or mentally limited person). Mere failure to object may not be construed as assent.

Assurance: A formal, written statement submitted to a federal agency attesting that an institution will comply with applicable rules governing research with human subjects.

Belmont Report: The Belmont Report consists of three basic ethical principles as a basic justification for human subjects' research decision-making and judgments. The three principles are: 1) Respect for persons, 2) Beneficence, and 3) Justice.

Consent: Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether to participate as a research subject.

Conflict of Interest: Any known interest, actual or potential, financial or non-financial, of a person (or of their spouse, dependent child, family member) that could affect, or could reasonably appear to affect, their judgment. Conflicts of interest often arise from financial relationships with a research sponsor or from intellectual property rights.

Exempt Research: Exempt research is research involving little, if any, associated risk to human subjects. This category of approval has very specific criteria and allows the research to be conducted under abbreviated and simplified rules. Six categories of research activity, as defined in the federal regulations for protecting research subjects, are inherently risk free, such as the secondary analysis of de-identified data. If research falls into one of the qualified categories, it may qualify for exemption.

Expedited Review: An IRB protocol review conducted by the IRB chair or an IRB member directed by the chair without requiring a review by the full IRB committee. The protocol must be minimal risk and meet additional qualifications.

Financial Conflict of Interest: Equity holdings in commercial sponsors, consulting fees, royalties, patent rights, honoraria, funding incentives for patient enrollment, stock options in commercial sponsors, referral or finder's fees, nonmonetary "perks" or rewards, post-study reward (e.g., vacation trip), etc.

International Conference on Harmonization: Provides a unified standard for the European Union, Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in those jurisdictions.

Research Proposal: A research proposal is a document that is written by a scientist that describes in detail a process for a proposed scientific investigation which is meant to persuade others to approve/fund their research project.

Research Protocol: A document that describes the objective(s), design, methodology, and statistical rationale of a research study.

Serious Adverse Event: An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life- threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

APPENDIX A

Collaborative Institutional Training Initiative (CITI) Training

Each PI who submits a human research or exempt research protocol to the 59 MDW IRB is required to complete CITI training in human research subject protection. Associate Investigators (AI), other investigators, research project directors, coordinators, or assistants; and medical monitors listed on the protocol must also complete this training. The Office of Research Protocol Support must receive documentation of PI training before IRB review of the protocol. Documentation of training for AIs, other investigators, and the Research Monitor must be received before final approval of the study is granted. This is one of several ways that the IRB ensures that investigators possess the appropriate knowledge and skills required to conduct the research protocol.

The Basic CITI Course contains four groups of modules that pertain to biomedical or social/humanistic/behavioral research. To complete an initial Basic CITI Course, follow the following steps:

- Go to CITI website to access the training courses.
- Click either "Register Here" as a new user or enter your Username and Password if you previously registered for a CITI account. News users should select "USAF-Wilford Hall" from the Participating Institutions drop- down menu and then complete the remainder of the registration process (e.g., enters username, password, name, e-mail address).
- Consider the research category (human use or exempt) and focus (biomedical or social/humanistic/behavioral) that you plan to conduct and select the appropriate training group:
- Group 1 – Biomedical research with human subjects
- Group 2 – Exempt biomedical research with human subjects
- Group 3 – Social/humanistic/behavioral research with human subjects
- Group 4 – Exempt social/humanistic/behavioral research with human subjects.
- Complete each training module for the group that you selected. The passing score is 80% for each module. Complete the post-test. The passing score is 80%. If you score <80%, on each module or on the overall score, the failed training modules will reset to allow you to retake those modules.

- After you complete the training, download the course transcript and print it for your records. The Office of Research Protocol Support at the CIS will automatically receive notification that you completed the training.

- This training is valid for 3 years from the initial training date and must be re-accomplished prior to the 3-year expiration date by completing the CITI Refresher Course. If an investigator's CITI training expires, they must remove from the research study until the training is re- accomplished. If the PI's CITI training expires, the IRB may decide to suspend the research until the PI re-accomplishes the training. The IRB may not approve a Continuing Review Report or amendment to a study, if the PI's training is not current. If a request is made to change the PI, the IRB may not approve the change, if the new PI does not have current CITI training.

The **Refresher CITI Course** is designed for investigators who previously completed a Basic CITI Course and are required to complete the 3-year re-certification requirement. To complete a **Refresher Basic CITI Course**, follow these steps:

- Go to CITI website to access the training courses
- Enter your Username and Password.
- Consider the research category (human use or exempt) and focus (biomedical or social/humanistic/behavioral) that you plan to conduct or are conducting and select the appropriate training group:
- Group 1 – Biomedical research with human subjects
- Group 2 – Exempt biomedical research with human subjects
- Group 3 – Social/humanistic/behavioral research with human subjects
- Group 4 – Exempt social/humanistic/behavioral research with human subjects.
- Complete each training module for the group that you selected. The passing score is 80% for each module. Complete the post-test. The passing score is 80%. If you score < 80%, on each module or on the overall score, the failed training modules will reset to allow you to retake those modules.
- After you complete the training, download the course transcript and print it for your records. The Office of Research Protocol Support at the CIRS will automatically receive notification that you completed the training.

Each PI, AI, other investigator, research coordinator or assistant, and Research Monitor must maintain current human research subjects' protections training; therefore, if these individuals' training lapses, the IRB will remove them from the study protocol. The IRB will not approve a continuing review report, amendment to the protocol, or request to change PI if the PI's training is not current.

Contact the 59 CIRS Office of Research Protocol Support for CITI training questions at: usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.mil

AALAS TRAINING INSTRUCTIONS FOR PRINCIPAL AND ASSOCIATE INVESTIGATORS

TO RECEIVE CREDIT FOR AALAS TRAINING, COMPLETE EACH COURSE LESSON AND EXAM IN EACH TRAINING MODULE

Go to AALAS Learning Library Website: https://www.aalaslearninglibrary.org/

1. Click **Enroll now!**
2. Under TYPE OF ENROLLMENT tab, "Are you enrolling yourself or a group?" Click **Myself (I am purchasing an individual account or using an Access Code to join a group.)** Click **CONTINUE**.
3. Under INDIVIDUAL ENROLLMENT TYPE tab, "Do you have an Access Code?" Click **Yes, I have an Access Code.** Click **CONTINUE**.
4. Under GROUP ACCESS CODE tab, "Enter your Access Code, which will associate your enrollment with your institution." enter **2317159 MDW/59CRD.** Click **CONTINUE**.

5. Under USERNAME AND PASSWORD tab, complete all requested information. Click **CONTINUE**.
6. Under CONTACT INFORMATION tab, complete all items as applicable, required items are identified with asterisk. Click **SUBMIT**.
7. Under WELCOME tab, click **CONTINUE**. This should bring you to the homepage where you will use your username and password to login. Then …
8. From the menu on the right side, click on **Animal Care and Use Courses.** [Here you will select the initial courses to take prior as part of the protocol submission process. Initial training remains current for three years.]
9. Initial course #1: click **+AALAS Courses**, click **+Anesthesia, Analgesia, and Surgery**, click Pain Management in Laboratory Animals and complete each course lesson and the course exam.
10. Initial course #2: from the menu on the left side, click on **Animal Care and Use Courses**, click **+AALAS Courses**, click **+LATG Courses: 2007 LATG Training Manual**, click LATG 06: Occupational Health and Safety (2007) complete each course lesson and the course exam.

11. Initial course#3: from the menu on the left side, click on **Animal Care and Use Courses**, click **+AALAS Courses**, click **+ALAT Courses: 2009 ALAT Training Manual**, click on the course required for the species used per the protocol and complete each course lesson and the course exam.

After the three-year initial training period, the following refresher courses are required:

1. Refresher course #1: click **+AALAS Courses**, click **+US Mandates and Guidelines**, click Public Health Service Policy on Humane Care and Use of Laboratory Animals and complete each course lesson and the course exam.
2. Refresher course #2: from the menu on the left side, click on **Animal Care and Use Courses**, click **+AALAS Courses**, click **+Bioethics**, click Ethical Decision-Making in Animal Research and complete each course lesson and the course exam.

Contact 59 CIRS Office of Research Protocol Support at (210) 292-6095/2977 for AALAS training questions.

Please provide the Office of Research Protocol Support with a copy of your AALAS training transcript.

APPENDIX B

DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

ST Policy Letter: OCT 10 2019
Supersedes: Ltr, dated 21 Sept 2018

MEMORANDUM FOR ALL ST STAFF

FROM: 59 MDW/ST
1632 Nellis St, Bldg. 5406, Rm. B154
JBSA-Lackland TX, 78236

SUBJECT: Policy on Applying for Grants via Online Grant Submission Sites

1. This policy memorandum outlines the submission process for scientific grant applications by intramural Principle Investigators (PIs) seeking ST support using the online grant submission systems: eRA Commons; Grants.gov; and Electronic Biomedical Research Application Portal (eBRAP), which support federal research awards.

2. ST staff conduct a technical and programmatic review of proposals providing expert advice and counsel concerning merit, adherence to call requirements and alignment with the wing research portfolio and the broader DHP corporate research investment in line with the policy memorandum, "Air Force Medical Service Guidance: Requirements, Roles & Responsibilities," 6 September 2017 and the ST Research and Acquisitions Advisory Committee Charter, 17 January, 2018.

3. PIs who are planning to apply using one of the online grant mechanisms are to contact the ST Business Official (BO) regarding submission intent as soon as possible. The proposal review is to be completed prior to acceptance of PI affiliation requests and generation of letters of support. The grant application is reviewed by me prior to submission by the ST BO within the online grants system. The BO, Mr. Jerry Spencer, will guide PIs through the specific steps for the internal review process and successful online submission.

4. For more information, please contact Mr. Jerry Spencer, at (210) 292-2303/2097 or by email: jerry.r.spencer.civ@mail.mil.

DEBRA M. NIEMEYER, Ph.D., DAF
Chief Scientist, 59th Medical Wing

Warrior Medics – Mission Ready – Patient Focused

DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

ST Policy Letter: OCT 10 2019
Supersedes: Ltr 2017-04, dated 2 Nov 2017

MEMORANDUM FOR ALL ST STAFF

FROM: 59 MDW/ST

SUBJECT: Knowledge Readiness Level (KRL) and Knowledge Transition Agreement (KTA) Policy (supersedes 59 MDW/ST policy letter 2017-04)

1. To improve our ability to transition the outcomes of our knowledge-based research projects to the clinical, readiness, and operational missions and better address Defense Health Agency (DHA) Procedural Instruction (PI) 3200.01 *Research and Development (R&D) Enterprise Activity* (9 Aug 2019), we are revising our policy for the development and use of knowledge transition agreements and the use of a revised readiness scale for assessing the maturity of knowledge-based projects/products for achieving effective completion and application. If the creation of a knowledge-based product is associated with the development of a materiel solution, the AFMS Technology Transition Agreement (TTA) process and the DoD Technology Readiness Level (TRL) chart (Table E-1 of the DoD Technology Readiness Assessment Guidebook, July 2009) will be used to manage and assess overall project maturity. The primary purpose for creating a knowledge transition agreement is to convey to all stakeholders, but specifically decision makers representing the intended user(s) of the knowledge product, what the expected outcome (deliverables) will be, how they will be generated, how long this process will take, and how the results are expected to be applied to the mission. If there are any disagreements on these points, the knowledge transition agreement will be revised. The objectives for using knowledge transition processes is to help focus precious Military Health System (MHS) medical research funding on:

a. Closing the gaps between research and practice

b. Optimizing health outcomes and care for the Warfighter and dependents/beneficiaries

c. Accelerating adoption of evidence-based practices

d. Streamlining health care processes and procedures

e. Reducing health care costs

2. Knowledge Transition Agreement (KTA): These agreements are established between the principal investigator (PI) of the research or equivalent and a designated transition partner who not only represents the intended user(s) of the knowledge which will be generated from the research, but has the decision authority to apply the knowledge product to a military mission (operational, clinical, education/training, or research). The KTA is quad-chart based to capture

the basic information of the research that is being performed, who is performing the research, who the end-user(s) is (are), the schedule for key events, the expected outcomes of the research (deliverables), and other important information that ensures all stakeholders are adequately informed. KTAs will be developed for all extramurally funded research and projects designated by 59 MDW research directors. The use of a KTA ensures the proposed research has clearly established end-states for transitioning the results that are supported by a senior end-user representatives who will apply the knowledge generated to effect a change in a process, policy, clinical practice guideline, or even as an impetus for developing a follow-on research study (proposal) if the research is successful. Approved KTAs will be reviewed at least annually, revised as necessary, and annotated with the date reviewed ("Current as of: _____").

3. Knowledge Readiness Level (KRL): the readiness levels of medical knowledge-based research are a method for identifying and reporting the current and projected maturity level of the *state-of-the science* for the medical research topic area that is being researched. The KRL chart in attachment 2 was developed by U.S. Army Medical Research & Development Command (USAMRDC) to identify to program managers and decision makers how much the proposed research will advance the knowledge of medical research topic area. Unlike a TRL, the KRL is not associated with the status or maturity of a project, as a knowledge-based research project that informs/enables another research effort may be successfully completed at a low KRL and never reach a KRL of 8 or 9 (implemented into practice).

4. For internal tracking, sharing, and reporting of the maturity level of a research project internally to the 59 MDW, the attached Project Readiness Level (PRL) may be used. The PRL is a method for identifying issues that are impacting the project schedule and reporting to key stakeholders for assistance and support. The categories in the attached KRL chart are intended to be broad-based and allow the chart to be applied to various types of research projects.

5. If you have any questions, please contact Dr. Scott Walter scott.f.walter.civ@mail.mil or (201) 292-7210.

DEBRA M. NIEMEYER, Ph.D., DAF
Chief Scientist, 59th Medical Wing

3 Attachments:
1. Knowledge Transition Agreement (KTA) Template
2. USAMRDC Knowledge Readiness Level (KRL) Chart
3. Project Readiness Level (PRL) Chart

See notes section below for guidance

Knowledge Project or Product Name

Knowledge Transition Agreement (KTA)

U.S. AIR FORCE Type of Research Effort

59 MDW

Research Study Description: Briefly explain the nature of the situation(s) that will be researched and the knowledge gaps that exist for the (clinical, training, education, or other)

Potential Impact: Briefly explain the impact of the knowledge gained to the military missions

Deliverables: List all deliverables that will be generated by the successful completion of this project

Performers/Role:
- 59 MDW (who is leading the study)
- List any/all collaborators

Status & Key Events:
CY2X: define first phase/year events
CY2X: define second phase/year events
CY2X: define third phase/year events & conclusion

End Users: List specific teams, missions, units, and/or organizations that will use/benefit from/be affected by this research

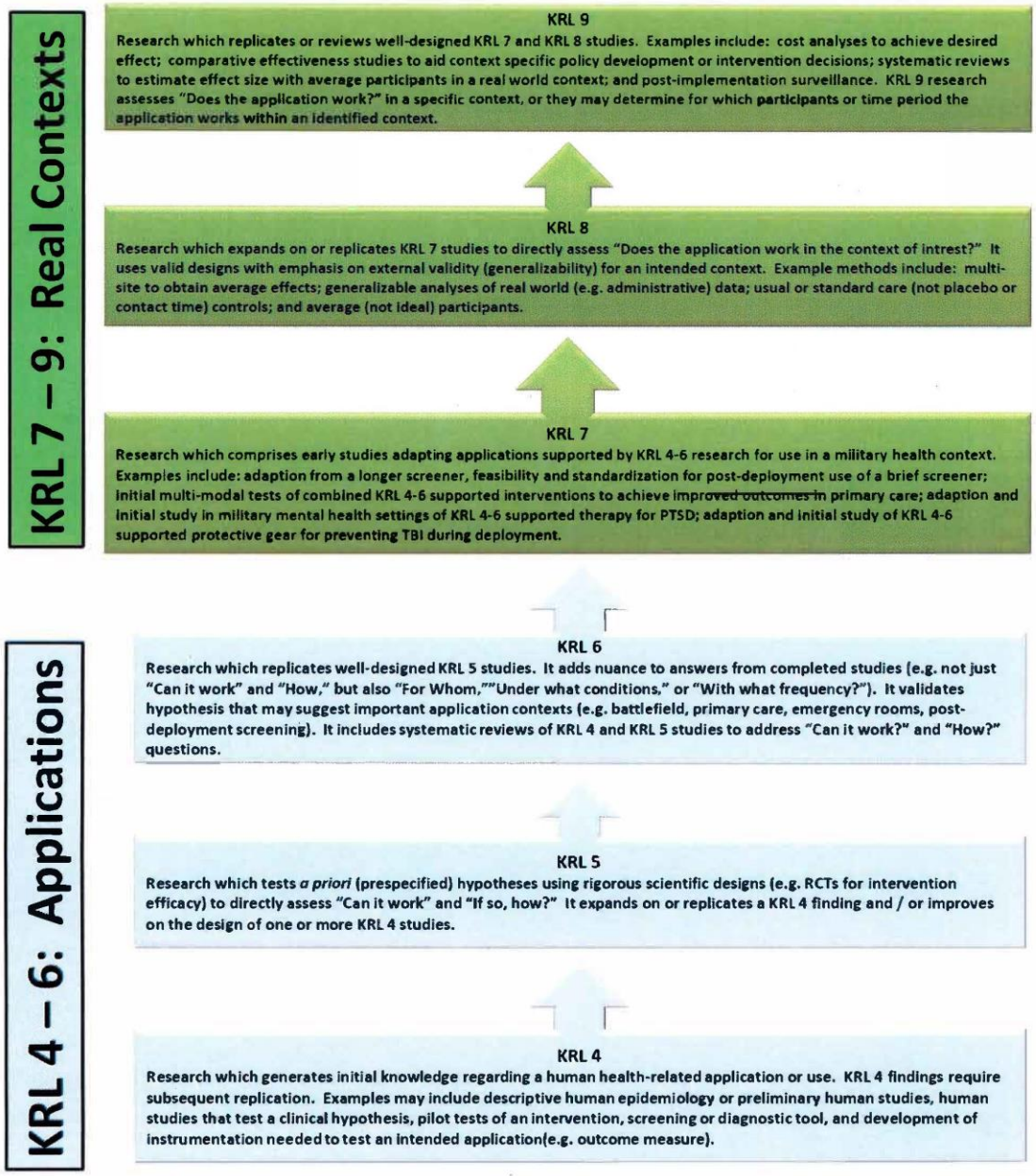
1. **Requirements**: AFMS ICL, Integrated Capabilities Document (ICD), Research Development Document (RDD), user memo (date signed/who), or other established end-user gap, requirement, desire, or request
2. **Maturity:**
   - **Current KRL (Date):**
   - **Next scheduled MS:** Pre-MDD
   - **Expected completion date:**
3. **IRB/IACUC: (Y/N):** N - must explain)
4. **Transition Partner:** _____(name & organization)_____
   Date KTA accepted: Month & Year
5. **Clinical Trial? (Y/N):** (N - must explain)

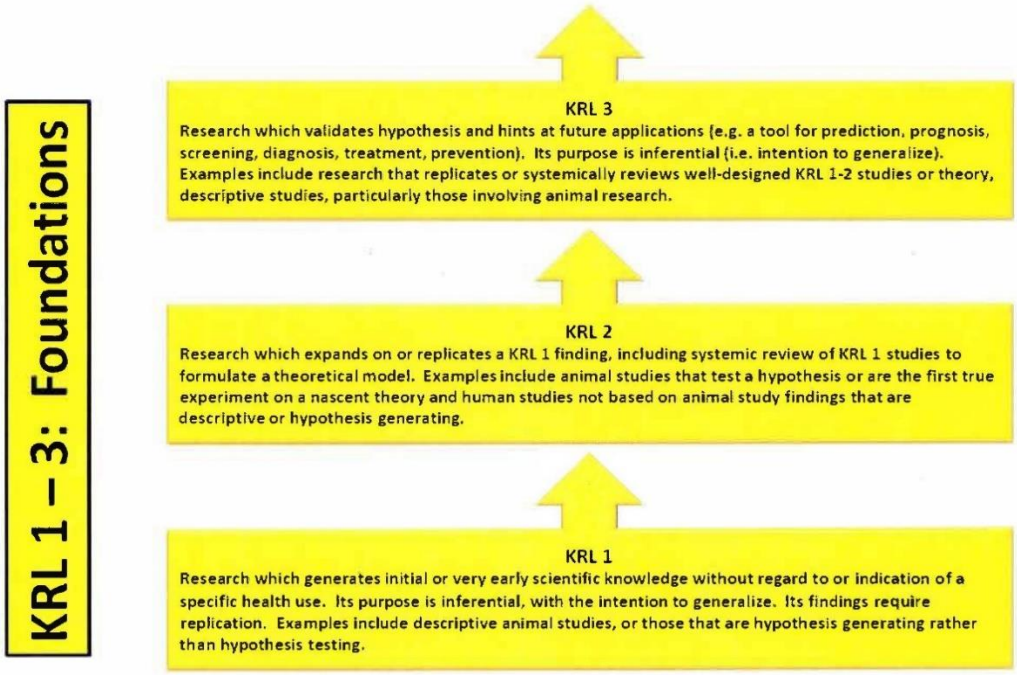
Budget: $K / DHP / Other / UFR

	Previous	FY19	FY20	FY21	FY22	FY23	Total
AFMS 6.2							
AFMS 6.3							
DHP 6.2/6.3			1.2M	1.2M	700K		1.9M
Other							
UFRs		700K					
Total		700K	1.2M	1.2M	700K		3.8M

Lead/PI: _____ *Integrity - Service - Excellence* Current as of: _____

Attachment 2: USAMRDC Knowledge Readiness Level (KRL) Chart




KRL 1 – 3: Foundations
KRL 3
Research which validates hypothesis and hints at future applications (e.g. a tool for prediction, prognosis, screening, diagnosis, treatment, prevention). Its purpose is inferential (i.e. intention to generalize). Examples include research that replicates or systemically reviews well-designed KRL 1-2 studies or theory, descriptive studies, particularly those involving animal research.
KRL 2
Research which expands on or replicates a KRL 1 finding, including systemic review of KRL 1 studies to formulate a theoretical model. Examples include animal studies that test a hypothesis or are the first true experiment on a nascent theory and human studies not based on animal study findings that are descriptive or hypothesis generating.
KRL 1
Research which generates initial or very early scientific knowledge without regard to or indication of a specific health use. Its purpose is inferential, with the intention to generalize. Its findings require replication. Examples include descriptive animal studies, or those that are hypothesis generating rather than hypothesis testing.

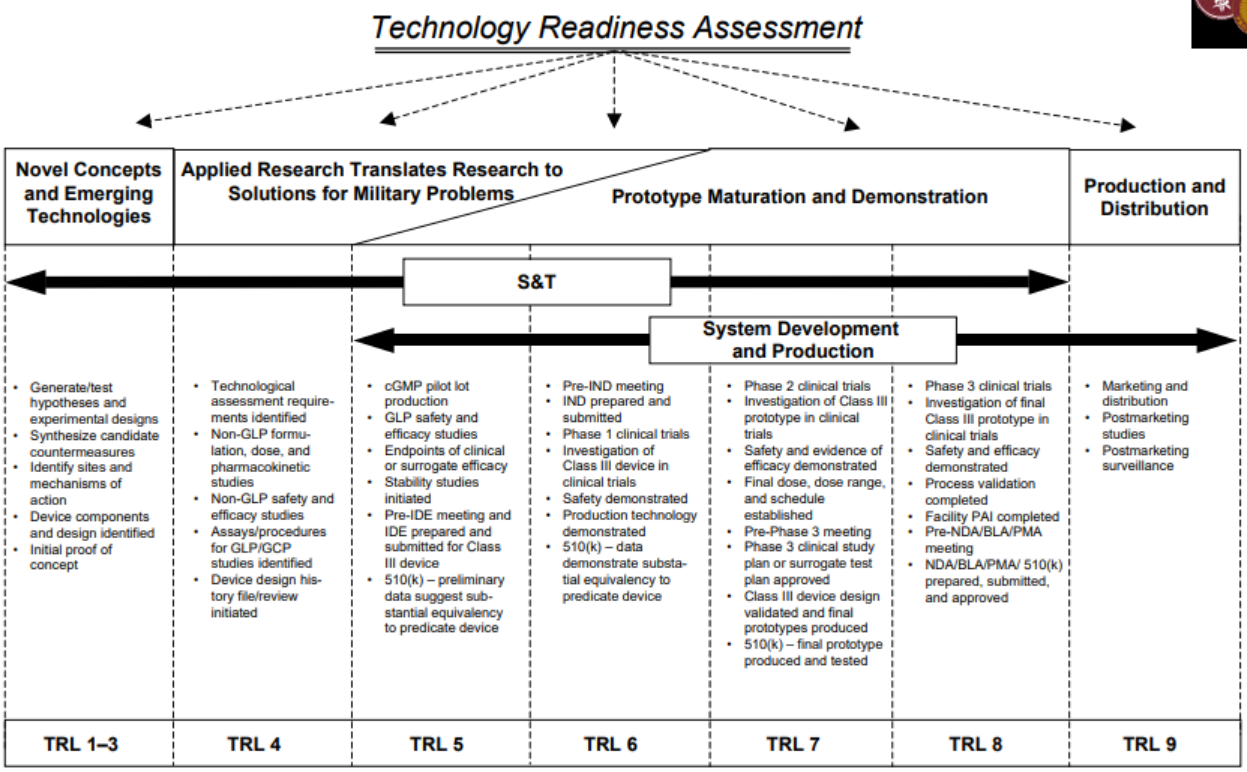


Figure E-1. TRLs in the Medical Materiel Regulatory Process

Note for Figure E-1: *The TRL descriptions are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. The S&T and acquisition PMs work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished, particularly with regard to TRL 5. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.*

Attachment 3: Project Readiness Level (PRL) Chart

Project Readiness Levels (PRL)

All deliverables must be listed in the research study plan and knowledge transition agreement (KTA), as well as shared with the transition partner (decision maker responsible for implementing knowledge product)

PRL 1	Initial approval of a topic or proposal that confirms a gap in knowledge exists that if answered, would enable generation of new or changes to existing clinical practice guidelines, guidance, health care standards, processes, study plan, or other knowledge-based product(s) for application to DoD mission (operational, clinical, training/educational). Changes may be considered optimization of existing processes or development of new ones to enhance operations.
PRL 2	Initial launch of study, funding on contract, IRB/IACUC approvals completed (as needed), CRADAs (or other agreements) established, recruitment initiated.
PRL 3	Active analytical and laboratory studies ongoing, data being actively collected, over 20 percent of planned data completed.
PRL 4	Active analytical and laboratory studies ongoing, data being actively collected, over 40 percent of planned data completed.
PRL 5	Active analytical and laboratory studies ongoing, data being actively collected, over 60 percent of planned data completed.
PRL 6	Active analytical and laboratory studies ongoing, data being actively collected, over 80 percent of planned data collected begin validating initial observations of a data and information;
PRL 7	Over 100 percent of planned data collected, IRB/IACUC closed (as appropriate), active data analyses ongoing and correlations noted; need for additional samples may reduce KRL; draft solutions and early results are presented to peers and end-users for review and heading check. Knowledge product must pass any developmental testing required. Solutions demonstrate efficacy (internal validity) and safety.
PRL 8	Initial analyses indicates data and solutions are sufficient to close the knowledge gap (achieve acceptable level of significance); draft knowledge products (refined solutions) are shared with end-users and knowledge transition partner representatives (as appropriate), and feedback used to refine for finalization and consideration of implementation. Knowledge product must pass any operational testing required. If appropriate, a package for the knowledge product is submitted to the FDA.
PRL 9	Knowledge products identified in the research study plan or KTA are delivered to the designated transition partner (e.g.: new/revised clinical practice guidelines, draft policy guidance memo, revised processes, a research study plan, or other knowledge-based product(s) for application to the DoD mission (operational, clinical, and/or training/educational). Draft articles are submitted to peer-reviewed literature or as abstracts to conferences for presentation as appropriate. The knowledge product submitted to the FDA is approved (if appropriate).

APPENDIX D

DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

MEMORANDUM FOR "(name of program agency)"
FROM: 59MDW/ST

SUBJECT: Letter of organizational support for "(Collaborator organization)" for the project entitled "(project title)" being submitted to the "(funding agency)" solicitation number "(solicitation number)".

1. I enthusiastically support the research proposal, "(project title)" to be conducted at JBSA-Lackland. The research activities consist of "(brief project summary of activities)". The long-term objective of this study will be "(objective)". An important translational aspect for the US Air Force and DoD in general would be "(benefits to the Air Force and DoD)".

2. As the 59th Medical Wing Chief Scientist, my role is to facilitate clinical and translational research, such as your work, which will address military needs and improve military care with the potential for technology transfer to the civilian sector.

3. You have my complete and enthusiastic support for this research proposal. ST staff will provide research support including lab space for the duration of the study, and in preparing presentations for scientific meetings and manuscript submission to peer-reviewed journals.

4. I look forward to assisting in any way and working closely with you and your team on this important study. This memo conveys our intent to work with "(collaborator organization)", but does not constitute a promise of funding. If there are any questions, please do not hesitate to contact my point of contact, "(DoD PI)" at (210) 292-XXXX (office) or by email at: XXXX.civ@mail.mil.

DEBRA M. NIEMEYER, Ph.D., DAF
Chief Scientist, 59th Medical Wing

Warrior Medics – Mission Ready – Patient Focused

Additional Notes:

- Ensure font and formatting are consistent throughout document
- Check spacing consistency, specifically after punctuation (two spaces after periods)
- Be consistent with casing in title headings (All caps vs mixed case)